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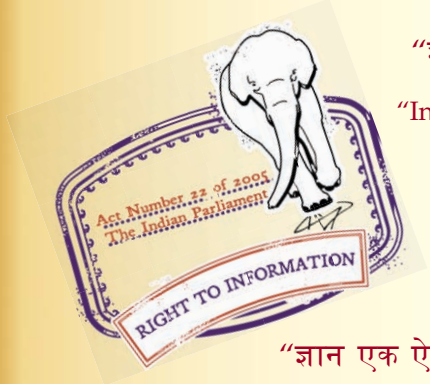

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"Knowledge is such a treasure which cannot be stolen"

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(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR EVACUATED TUBES FOR BLOOD SPECIMEN COLLECTION (VACUTAINERS)

UDC 615·014·8 : 616-072·5

INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

Gr 4

August 1984

Indian Standard

SPECIFICATION FOR EVACUATED TUBES FOR BLOOD SPECIMEN COLLECTION (VACUTAINERS)

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Indian Standard

SPECIFICATION FOR EVACUATED TUBES FOR BLOOD SPECIMEN COLLECTION (VACUTAINERS)

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 27 March 1984, after the draft finalized by the Medical Glass Instruments and Appliances Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard is based on ISO/TC76 DP 6710 draft proposal for 'Evacuated tube for blood specimen collection' issued by the International Organization for Standardization.

0.3 A separate standard covering guidance for using evacuated tubes for blood specimen collection including the different techniques of collection' and preservation, is under preparation.

0.4 These tubes are intended to be used with double pointed blood collection needles, thus providing a closed system for specimen collection and transportation.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS :2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard specifies requirements for single use evacuated blood specimen collection tubes' intended primarily for haematological, biochemical and serological use.

1.2 This standard covers the tubes sizes having nominal capacities up to 20 ml.

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*Rules for rounding off numerical values (revised).

2. TERMINOLOGY

2.0 For the purpose of this standard, the following definitions shall apply.

2.1 **Container** — The vessel to contain the specimen.

2.2 Tubes — The glass tube of the container that contains the specimen.

2.3 **Closure** — The component by which the tube of container is closed and the vacuum maintained in the tube.

2.4 **Container Interior** — Those inside surfaces of the tube and closure which come into contact with the blood specimen.

2.5 **Additive** — Any ingredient including tube coating or closure coating or anticoagulant or any other material that is placed in the containers.

2.6 **Sterile** — Describes the condition of the interior of a container which has been subjected to an approved steriiising process.

2.7 **Holder** — In which evacuated tube will slide for obtaining blood specimen. The holder may be of fixed type or screwed type. The fixed type is for single use only.

2.8 **Needle** — Double pointed needle with a hub which shall fit the holder, and puncture the closure of the container for obtaining the blood specimen.

2.9 **Sheath** — Sleeve type covering for the needle.

3. MATERIALS

3.1 The tube of the container system shall be made from clear transparent glass other than soda lime glass that allows an adequate undistorted view of the contents. It shall have sufficient physical strength to withstand normal use. It shall be capable of retaining the required vacuum for the stated shelf life.

3.2 The closure of the container system shall be made of rubber used for medical purposes. It shall provide for the needle puncture and reseal. It shall hold vacuum for stated shelf life.

3.3 All materials used in the construction of the container and any additives and coatings shall not influence the results obtained when the container is used as intended.

3.4 Holder material shall be either glass or plastic.

3.5 Needle cannula material shall be of stainless steel as specified in IS : 3317-1983".

3.6 Needle hub and its sheath may be of plastic material.

4. SHAPE, DIMENSIONS AND CAPACITY

4.1 Exterior of tube and closure shall be so designed as to allow for use with blood-collecting needle and holders as shown in Fig. 1 and 2.

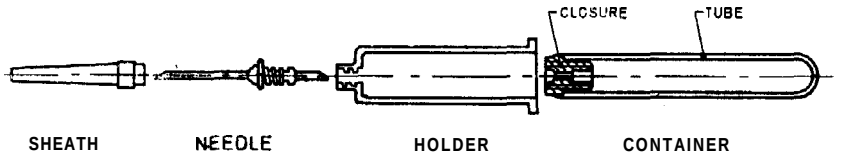

FIG. 1 DETAIL OF COMPONENTS

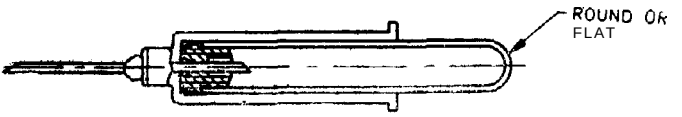

FIG. 2 EVACUATED TUBES FOR BLOOD SPECIMEN COLLECTION

4.2 The vacuum draw test specified in Appendix A shall apply to all types of containers. When tested by the method described in Appendix A the volume of water used shall be within ± 5 percent of the nominal capacity of the container. This shall be a type test.

4.3 For containers without an additive there shall be sufficient free space (minimum 2 percent of its capacity) to allow adequate mixing by mechanical or manual means.

4.4 For containers with an additive there shall be sufficient free space (not less than 2 percent and not more than 15 percent of its rapacity) to allow adequate mixing by mechanical or manual means.

4.5 The capacity and dimensions of glass tube shall be in accordance with Table 1.

*Specification **for** needles, hypodermic (*first revision*).

TABLE 1 CAPACITY AND DIMENSIONS OF GLASS TUBE

(Clause 4.5)

GROUP	CAPACITY	OUTSIDE DIAMETER OF TUBE	TOLERANCE ON OUTSIDE DIAMETER	LENGTH OF TUBE, NOMINAL
	ml	m m	m m	m m
(1)	(2)	(3)	(4)	(5)
1	2	10·25	± 0·25	47
	3	10·25	± 0·25	64
	4	10·25	± 0·25	a2
	5	10·25	± 0·25	103
	6	10·25	± 0·25	120
2	5	13·00	± 0·25	75
	7	13·00	± 0·25	100
	9	13·00	± 0·25	125
3	7	16·00	± 1·00	75
	IO	16·00	± 1·00	100
	15	16·00	± 1·00	127
	20	16'00	± 1·00	165

4.6 The double pointed needle with hub shall have diameter and length in accordance with Table 2.

TABLE 2 **DIAMETER AND LENGTH OF DOUBLE POINTED NEEDLE WITH HUB**

NOMINAL DIAMETER	EXTERNAL DIAMETER		BORE OF NEEDLE, Min	EXPOSED LENGTH IN FRONT OF THE HUB	EXPOSED LENGTH AT THE BACK OF THE HUB BELOW THE HOLDER SHOULDER
	Min	*Max*			
(1)	(2)	(3)	(4)	(5)	(6)
m m	m m	m m	m m	m m	m m
0·7	0'70	0·73	0·39	25	16
0·7	0·70	0·73	0·39	40	16
0·8	0·80	0·83	0·50	25	16
0·8	0'80	0.83	0·50	40	16
0·9	0·86	0.91	0·56	25	16
0·9	0·86	0.91	0·56	40	16

4.7 The both ends of the needle shall have short bevel in accordance with IS :3317-1983*.

4.8 These needles are for single use only.

4.9 Minimum length of the holder from its shoulder shall be in accordance with Table 3,

TABLE 3 LENGTH OF THE HOLDER

GROUP NUMBER	LENGTH, *Min*
	mm
1	38
2	45
3	55

4.10 If the needle is not fixed in the luer tip of the holder and the hubbed needle are used there shall be sufficient threads both on the needle hub and on the tip of the holder so that the needle is locked in place with the mating holder.

4.11 When the multiple sample needle is used, the needle end in the rear of the hub is covered by the thin wall natural rubber tubing 1 to 2 mm more than its exposed length. It shall be capable of collapsing when the needle is punctured into closure and with its elasticity it closes the exposed length of the needle completely when the tube is withdrawn along with closure.

4.12 Sheath sleeve dimensions shall be such that it is minimum 2 mm more than the exposed length of the needle on both sides.

5. CONSTRUCTION AND WORKMANSHIP

5.1 The closure shall be so designed that it can be removed by gripping with fingers or by mechanical extractors.

5.2 The closure shall be so designed that it shall not be removed or loosened when used to collect a blood specimen with a blood collecting needle.

5.3 The container holding the specimen, when centrifuged, shall be capable of withstanding an acceleration of 3 000 g (g = 9·806 65 m/S^2) in a longitudinal axis for 10 minutes.

*Specification for needles, hypodermic (*first* revision).

NOTE 1 — Care is required to ensure that the tube is correctly supported and adequately balanced in the centrifuge bucket.

NOTE 2 — If the tube projects above the centrifuge bucket the closure should not rest on the rim of the bucket during centrifuging because these containers are not intended to withstand the force to which they might then be subjected.

5.4 The container and the holder shall not have a sharp edge, projection or roughness of the surface capable of accidently cutting, puncturing or abrading the skin of the user.

5.5 The holder shall have outward flange on the one end. The flange shall have two flat sides — one opposite the other to prevent rolling of holder. The flange shall be of ample size to give a finger hold.

5.6 Needle shall be fitted concentric in the holder. The cannula shall be as specified in IS :3317-1983*.

5.7 Container, needle and holder shall be free from foreign matter.

5.8 The proximal end of the tube shall be suitably shaped to form a flat or concave surface to facilitate the thumb pressing it.

6. STERILIZATION

6.1 All containers shall be sterilized and shall satisfy the requirements of IS :10150-1981†. The container shall maintain sterility for the stated life.

6.2 Where hubbed needles are supplied separately in sheath the needle and the interior of the sheath shall be sterile and shall satisfy the requirements of IS :10150-1981†. The sheath and the needle shall maintain the sterility for the stated shelf life.

6.3 Where needles are fixed in the holder, there shall be a sheath for this needle and the complete holder with needle shall satisfy the sterility requirements of IS : 10150-1981† and they shall maintain the sterility for the stated shelf life.

7. LIMITS OF INTERFERENCE

7.1 Where containers are provided for the estimation of specific 'substances, such as sodium, potassium, etc, they may be labelled as being free from contamination if they give a concentration of that substance which is less than 1 percent of the level of the mean of the reference range for that substance.

*Specification **for needles, hypodermic (first *revision*).**

†Guide **for sterilization of medical products.**

7.1.1 Testing for contaminants shall be carried out according to the latest Indian Pharmacopoeia or by means of a definitive or reference method where such method is available. If there is no available definitive or reference method then a method in common usage may be used provided that the method is specified.

8. TESTS

8.1 The closure shall not become loose during mixing when being tested in accordance with the method specified in Appendix B.

8.2 When the closed tube is tested for leakage in accordance with the method specified in Appendix B, no trace of sodium fluorescein (uranine) shall be detectable in the water in which the tube has been immersed.

8.3 When the container is filled to its nominal capacity with a sodium fluorescein solution (25 g/litre) it shall not leak when inverted during exposure to an atmospheric pressure of 10 kPa.

8.4 Needle when fixed in hub or in luer tip of the holder shall satisfy test given in IS : 3317-1983* for security of swaging.

9. ADDITIONAL REQUIREMENTS

9.1 When one of the anticoagulants specified in Appendix C is used, the concentration shall be as indicated therein.

9.2 At the time of use with an anticoagulant the amount of blood collected shall be within ±5 percent of the stated volume. If antimycotic agents are added to liquid additives in the tube for growth inhibition and preservation of sample, the package label shall reflect such additives.

10. ANTICOAGULANT CODE

10.1 The following code indicates whether or not an anticoagulant has been used, and identifies the anticoagulant by the use of a letter coding:

Anticoagulant	*Code*
EDTA	K E
Potassium oxalate	K X

*Specification for needles, hypodermic (*first revision*).

Trisodium citrate	9 NC 4 N C (figures denote ratio between blood and anticoagulant)
Fluoride oxalate	F X
Ammonium and potassium oxalate	A K X
Lithium heparin	L H
Sodium heparin	N H
ACD	ACD
None	Z

NOTE — **Because of the amount of printing necessarily included on the container labels, the anticoagulant identification letters have been kept to a minimum and for this reason the chemical formulae have not been used.**

10.2 The volume in ml the container is designed to hold, shall be added after the code letters.

10.3 Code of the anticoagulant shall be marked according to 10.1 separately.

10.4 And if any other additive is added in the container **it** shall be marked separately.

11. MARKING

11.1 Each shelf pack shall be marked with the following:

a) Name, address and recognized trade-mark of the manufacturer;

b) Batch number;

c) Date of manufacture or expiry date;

d) Description of contents; and

e) Storage conditions.

12. PACKING

12.1 Each shelf pack shall be packed as agreed to between the purchaser and the manufacturer. However the requirements of packing as specified in IS:10150-1981* shall be followed.

*Guide for sterilization of medical products.

APPENDIX A
(Clause 4.2)

VACUUM DRAW TEST

A-l. REAGENT

A-f.1 Distilled water.

A-2. APPARATUS

A-2.1 A balance capable of weighing in milligrams.

A-2.2 Reservoir for distilled water connected to plastic tubing, 1 m in length.

A-2.3 Double ended needle conforming to Table 2.

A-3. PROCEDURE

A-3.1 Number the tubes to be tested. Weigh each tube and record the mass. Fill each tube with distilled water whilst the tube is in the horizontal position and using the double ended needle. Leave the needle and container in place for 2 minutes before removing the container. Clear any water from the exterior surface of the closure and r-e-weigh the container.

A-4. **CALCULATION**

A-4.1 Calculate the volume of water used (1 g = 1 ml of distilled water).

APPENDIX B
(Clauses 8.1 *and 8.2)*

TEST FOR LEAKAGE OF A CONTAINER

B-l. REAGENT

B-l.1 Dissolve 25 g of sodium fluorescein (uranine) in 6 percent (*m/v*) dextran 70 in 0·15 molar saline solution, and make up to 1 litre of the dextran solution.

B-2. APPARATUS

B-2.1 A reservoir for the sodium fluorescein solution attached to 1 m plastic tubing and fitted with a 0·9 mm double ended needle (see Table 2).

B-2.2 A source of longwave ultra-violet light.

B-3. PROCEDURE

B-3.1 Fill the container to its nominal capacity (as in Appendix A) and when filled remove the container from the needle and wipe the closure free of any contamination by sodium fluorescein.

B-3.2 Place the tube on a roller type mixture for 20 minutes. Inspect the stopper for any evidence of leakage. If none is present proceed to the next stage.

B-3.3 Expose the inverted container and contents for 2 hours to a temperature of -20 +4°C. Allow to return to room temperature and then expose to 37°C for 2 hours. Immerse the inverted container in the minimum quantity of water to completely cover the closure and check for traces of fluorescein by ultra-voilet light.

APPENDIX C
(Clause 9.1)

CONCENTRATIONS FOR ANTICOAGULANTS

C-l. CONCENTRATIONS FOR ANTICOAGULANTS

C-l.1 Concentrations for anticoagulants shall be as given below:

a) *EDTA* — 1'19 ±0·2 mg/l ofanhydrous EDT.4 (acid) (≃ 4 nmol/l) per ml of blood*.

b) *Fluoride Oxalate* —1·0±0·1 mg/l of sodium fluoride (24 nmol/l) and 3·0±0·3 mg/l of potassium oxalate (18 nmol/l) per ml of blood.

c) *Potassium Oxalate* —1·2±0·12 mg/l of ammonium oxalate (≈10 nmol/l) and 0·8±0·08 mg/l of potassium oxalate (≈10 nmol/l) per ml of blood.

***EDTA is calculated as the anhydrous salt of sequestric acid. Appropriate alteration will have to be made to compensate for the actual salt used and its water of crystallization.**

d) ***Trisodium Citrate***

1) Trisodium citrate solution at a concentration of $0{\cdot}109 \pm 0{\cdot}010$ mol/l,

2) One volume of trisodium citrate solution to nine volumes of blood for coagulation studies, and

3) One volume of trisodium citrate solution to four volumes of blood for measurement of erythrocyte sedimentation rate by the Westergren method.

e) *Heparin* — *15* $\pm 2{\cdot}5$ international units per ml of blood.

f j ***Acid Citrate Dextrose*** — $0{\cdot}15 \pm 0{\cdot}015$ ml of acid citrate dextrose N.I.H. solution A per ml of blood.

Dissolve trisodium citrate dihydrate 22 g, citric acid monohydrate 8 g, dextrose 25 g, with water to 1 litre.

INTERNATIONAL SYS TEM OF UNITS (SI UNITS)

Base Units

QUANTITY	UNIT	SYMBOL
Length	metre	m
Mass	kilogram	kg
Time	second	S
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

QUANTITY	UNIT	SYMBOL
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

QUANTITY	UNIT	SYMBOL	DEFINITION
Force	newton	N	1 N = 1 $kg.m/s^2$
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m^2
Frequency	hertz	HZ	1 Hz = 1 $c/s\ (s^{-1})$
Electric conductance	siemen	S	I S = 1 A/V
Electromotive force	volt	V	1 V = 1 W/A
Pressure, stress	pascal	Pa	1 Pa = 1 N/m^*